

**PANA0001-100 (formerly PANA-0002)
PATENT**

**Serial No. 09/753,892
Filed: January 3, 2001**

REMARKS

Status of the Claims

Claims 43-79 are pending in the application.

Claims 43-68 and 70-79 have been rejected.

Claim 69 has been objected to.

By way of this amendment, claims 53, 54 and 69-79 have been canceled, and claim 48 and 61 have been amended.

Upon entry of this amendment, claims 43-52 and 55-68 will be pending.

Summary of the Amendment

Claim 48 has been amended to incorporate the subject matter of claim 53, which has been canceled as being redundant in view of the amendment of claim 48.

Claims 54 and 70-79, which have been canceled, are directed at methods of treating exposure to chemical mutagens. Applicant intends to pursue this subject matter in a continuation application.

Claim 61, which is an independent has been amended to incorporate the subject matter of objected to claim 69, which has been canceled as being redundant in view of the amendment of claim 61. The subject matter of claim 61 as amended is identical to that of claim 69.

No new matter has been added.

Objections

An objection has been made to claim 60 for containing an incorrect status identifier. The claim now contains a correct status identifier.

Applicant notes that remarks concerning claims 53 and 61 and claims 54 and 70. The subject matter of claim 53, which is now incorporated into amended claim 48, is not identical to amended claim 61. Claims 54 and 70 have been canceled.

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Rejection under 35 U.S.C. § 112

Claims 48-52 and 54-57 have been rejected under 35 U.S.C. § 112, first paragraph, because it is asserted that while being enabled for treating an individual exposed to ionizing radiation, it is asserted that the specification does not enable methods for treating individuals exposed to other stimuli. It is asserted that specification does not enable one skilled in the art to which it pertains or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Applicant respectfully disagrees.

In an effort to advance prosecution, Applicant has amended claim 48 to incorporate the limitation of claim 53. The subject matter of claim 48 is now identical to that of claim 53, which has been canceled in favor of amended claim 48. Claim 48 is thereby limited to subject matter deemed enabled. Each of claims 49-52 and 54-57 contain the limitations of claim 48 and are also limited to subject matter deemed enabled.

Applicant respectfully requests that the rejection of claims 48-52 and 54-57 under 35 U.S.C. § 112, first paragraph, be withdrawn.

Prior Rejection under 35 U.S.C. § 102

Claims 43-53 and 55-68 stand rejected under 35 U.S.C. § 102(b) as being anticipated by or under 35 U.S.C. § 103(a) as being obvious in view of Sekiguchi et al. (US 3,803,116).

Sekiguchi et al. disclose a method of treating cancer patients who are being treated with ionizing radiation by administering to such individuals low molecular weight DNA derived from non-human sources such as fish sperm or non-human mammalian organ DNA. Sekiguchi et al. specifically discloses that because the DNA is non-human, in order to avoid "hereditary danger of genetic mutation" the non-human DNA should be lower molecular weight (200,000-500,000). As the Examiner has indicated, 200K-500K is about 300-800 basepairs of foreign DNA. Accordingly, Sekiguchi does not anticipate

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the claimed invention. Moreover, nothing is Sekiguchi teaches or suggests the use of 300-800 basepairs of human DNA.

Applicant has pointed out that Sekiguchi teaches the use of 300-800 basepairs of foreign DNA to reduce risks specifically associated with the use of foreign DNA. Sekiguchi teaches the specific size because it is foreign DNA. The motivation to use the size is because of the risks associated with foreign DNA. Sekiguchi's teachings are quite clear and unambiguous in this regard. The use of "lower molecular weight DNA" instead of high molecular weight DNA by Sekiguchi arises from Sekiguchi's teachings that foreign DNA had to be reduced in size to avoid dangers associated with the use of high molecular weight foreign DNA.

The Office urges that at the time of the present invention, human DNA was commercially available and thus those skilled in the art would replace the foreign DNA taught by Sekiguchi et al. with human DNA. It is the position of the Office as stated in the paragraph bridging pages 5 and 6 of the Official Action that

Sekiguchi would have suggested to one skilled in the art that if human DNA were available in sufficient quantity, it would be preferable over foreign DNA to further reduce the risk of mutation, and that the size of the human DNA to be used would be the same as was shown to work with foreign DNA, since there is no reason to use any other size of DNA.

There is no basis in Sekiguchi to support the Office's speculation of what Sekiguchi would have suggested however. Rather, the specific teachings of Sekiguchi indicate that there would be no reason to use lower molecular weight human DNA since the risks and dangers which led Sekiguchi to reduce the size of the DNA were because it was not human. Sekiguchi teaches to reduce the size of the DNA because it is foreign, not human. It cannot be properly construed as teaching or suggesting to reduce the size of the DNA if it is human.

Applicant respectfully notes that the evidence of record shows an improved result when using DNA from the same species within the claimed size range versus the results

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seen when using DNA from a different species within the claimed size range. In the Declaration of Leonid A. Yakubov filed pursuant to 37 CFR 1.132, the data in Paragraph 7 (page 3-4) and Exhibit 4 shows improved survival using mouse DNA versus non-mouse DNA to treat irradiated mice.

Applicant respectfully urges that a prima facie case of obviousness cannot be made based upon Sekiguchi because Sekiguchi clearly teaches away from using human DNA of the size range claimed. Moreover, Applicant's data shows the unexpected advantage of using human DNA in the claimed size range. As pointed out by the Examiner, both Wilczok and Ledoux, which do not teach or suggest using DNA of the claimed size range, teach that there was no difference between effectiveness of homologous versus heterologous DNA. Thus even if someone were to modify Sekiguchi by using low molecular weight homologous instead of low molecular weight foreign DNA, they would not expect an improvement in results. Such surprising and unexpected results clearly support a finding of non-obviousness even if a prima facie case of obviousness were found to exist.

Claims 43-53 and 56-60 are neither anticipated by Sekiguchi et al. nor obvious in view of it. Claims 61-68 have been amended to incorporate the limitation of claim 69. Applicant respectfully requests that the rejection of claims 43-53 and 56-68 under 35 U.S.C. § 102(b) as being anticipated by or under 35 U.S.C. § 103(a) as being obvious in view of Sekiguchi et al. (US 3,803,116) be withdrawn.

Allowable Subject Matter

Claim 69 has been objected to as being depended upon a rejected base claim. It is stated that it would be allowable if rewritten in independent form. Applicant has amended claim 61 to incorporate the subject matter of claim 69. As amended, claim 61 is an independent claim with identical to the subject matter of claim 69. Applicant respectfully urges that claims 61-68 are allowable.

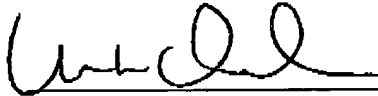
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Conclusion

In view of the foregoing, Applicant submits that the claims as amended are in condition for allowance, and an early Office Action to that effect is earnestly solicited. Applicant invites the Examiner to contact the undersigned at (215) 665-5592 to clarify any unresolved issues raised by this response.

Respectfully submitted,



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